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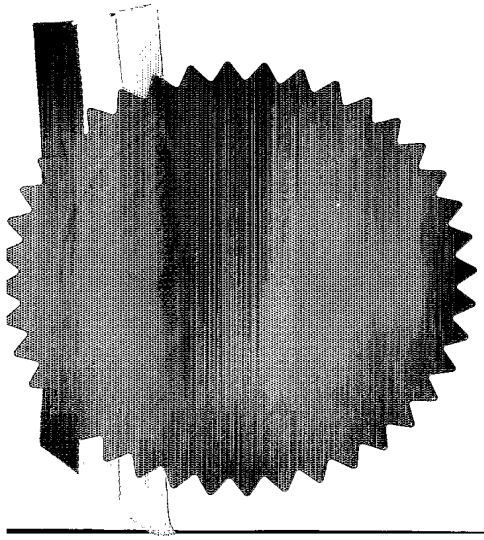
I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	S2004/0201
Date of Filing	26 March 2004
Applicant	BRIVANT RESEARCH & DEVELOPMENT, an Irish company of Unit 6, Campus Innovation Center, Newcastle Road, Galway, Ireland

Dated this 5 day of April 2005.



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FORM NO. 1

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

S040201

The Applicant(s) named herein hereby request(s)

[ ] the grant of a patent under Part II of the Act

[X] the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)

Name

BRIVANT RESEARCH & DEVELOPMENT LIMITED

Address

Unit 6, Campus Innovation Center, Newcastle Road, Galway, Ireland.

Description/Nationality

An Irish company.

2. Title of Invention

"A guide wire for use in re-canalising a vascular occlusion in a human or animal subject"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed by Applicant(s) to be the inventor(s)

HENRY LUPTON and MARK BRUZZI

Address

An Irish citizen of Minehill House, Renville West, Oranmore, Galway, Ireland.
An Irish citizen of Shantalla Place, Galway, Ireland.

5. **Statement of right to be granted a patent (Section 17 (2) (b))**
The applicant has derived the right to be granted a Patent from the inventor by virtue of a Deed of Assignment dated March 25. 2004

6. **Items accompanying this request – tick as appropriate**

(i) [X] Prescribed filing fee (€60.00)

(ii) [ ] Specification containing a description and claims

[X] Specification containing a description only

[X] Drawings referred to in description or claims

(iii) [ ] An abstract

(iv) [ ] Copy of previous application(s) whose priority is claimed

(v) [ ] Translation of previous application whose priority is claimed

(vi) [ ] Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. **Divisional Application(s)**
The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: .....
Filing Date: .....

8. **Agent**
The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted –

Name	Address
F.F. GORMAN & CO.	15 Clanwilliam Square, Dublin 2, Ireland.

9. **Address for Service (if different from that at 8)**
F.F. GORMAN & CO., at its address as recorded for the time being in the Register of Patent Agents.

Signed

BRIVANT RESEARCH & DEVELOPMENT LIMITED

BY: _____

CAPACITY: Director

Date March 26. 2004

"A guide wire for use in re-canalising a vascular occlusion in a human or animal subject"

The present invention relates to a guide wire for use in a re-canalising process of a vascular occlusion in a human or animal subject, and in particular, for re-canalising a blocked or partially blocked artery, for example, in the cardiovascular system, although the invention is not limited to the guide wire for such use.

Guide wires are commonly used for guiding a catheter carrying a therapeutic or other device to a remote location in the vascular system of a subject. For example, where a vessel is occluded or partially occluded, a guide wire is used for guiding a catheter which may carry a balloon at its distal tip or a stent for locating in the artery in the occluded part thereof for maintaining a passage through the occlusion. However, prior to the insertion of the stent or other such device, the occlusion must be penetrated in order to commence opening of a passage therethrough.

Guide wires are provided for penetrating such occlusions or partial occlusions prior to the insertion of the catheter over the guide wire. U.S. Patent Specification No. 6,348,040 of Stalker, et al discloses such a catheter which is provided with a vibrating tip. However, a disadvantage of the guide wire disclosed in this U.S. Patent specification is that in order to provide the vibrating tip, relatively expensive and, more importantly, cumbersome equipment is required, which must be attached to the guide wire. U.S. Patent Specification No. 6,669,652 of Anderson, et al discloses a guide wire in which a helical coil extending around a core wire of the

guide wire adjacent the distal end extends beyond the distal end of the core wire, and tapers to a distal point for penetrating the occlusion as the guide wire is urged forwardly. One disadvantage of the guide wire disclosed in this U.S. specification is that due to the fact that the tip is pointed, there is a danger of the tip penetrating the wall of a vessel of the vascular system as the guide wire is being urged to the occlusion. Another disadvantage of this guide wire is that the portion of the helical cord which extends beyond the distal end of the core wire is relatively flaccid, and thus renders the guide wire difficult to guide through the vascular system. U.S. Patent Specifications Nos. 5,527,298 and 5,127,917 disclose guide wires in which the distal end of the guide wires terminate in bulbous distal tip portions. The distal tip portions are of transverse cross-sectional area significantly greater than the transverse cross-sectional area of the guide wire, and taper to a distal point. The distal point facilitates penetration of the occlusion, and the tapering portion facilitates in easing the guide wire through the occlusion. However, a disadvantage of the guide wires disclosed in these two U.S. Patent specifications is that due to the fact that the transverse cross-sectional area of the bulbous distal tip portions are significantly greater than the transverse cross-sectional area of the guide wire, difficulty is experienced in subsequently urging a catheter over the bulbous tip portions.

There is therefore a need for a guide wire which is suitable for use in a re-canalising process of a vascular occlusion in a human or animal subject.

The present invention is directed towards providing such a guide wire.

According to the invention there is provided a guide wire for use in a re-canalising process for re-canalising a vascular occlusion in a human or animal subject, the guide wire extending between a proximal end and a distal end and terminating at its distal end in a terminal member extending axially from the guide wire, the terminal member tapering to a transversely extending distal edge for engaging and gradually opening the occlusion as the terminal member is urged therethrough.

In one embodiment of the invention the transverse cross-sectional area of the terminal member is substantially similar to the transverse cross-sectional area of the guide wire adjacent the terminal member.

In another embodiment of the invention the terminal member and the guide wire adjacent the terminal member are of circular transverse cross-section, and are of substantially similar diameters.

In one embodiment of the invention the terminal member terminates in a chisel type distal end defining the transversely extending distal edge, and preferably, the transverse width of the distal edge is substantially similar to the corresponding width of the guide wire adjacent the terminal member, and preferably, is substantially similar to the diameter of the terminal member.

In one embodiment of the invention the guide wire comprises an elongated core wire extending from the proximal end to the distal end, and preferably, the terminal

member is secured to the distal end of the core wire.

Ideally, the core wire is of circular transverse cross-sectional area, and advantageously, is flattened to terminate at its distal end in a distal portion of rectangular transverse cross-section for facilitating bending thereof for axially offsetting the terminal member for facilitating guiding of the guide wire through a branching network of a vascular system.

In one embodiment of the invention a reinforcing means is provided on the distal portion of the core wire for minimising axial twisting of the flattened distal portion.

In a further embodiment of the invention the flattened distal portion defines a pair of respective opposite major surfaces, and the respective opposite major surfaces define a major plane parallel to the major surfaces, and ideally, the flattened distal portion is curved in the major plane for facilitating guiding of the guide wire through a branching network of a vascular system.

In another embodiment of the invention a sleeve extends along the core wire from the distal end thereof, and terminates at a location intermediate the distal end and the proximal end. Advantageously, the external diameter of the sleeve is substantially similar to the external diameter of the terminal member.

Preferably, the sleeve comprises a helical coil wound around the core wire adjacent the distal end thereof.

In one embodiment of the invention a plug extends axially from the terminal member for engaging an internal bore defined by the helical coil for securing the helical coil to the terminal member.

In another embodiment of the invention an axial bore extends into the terminal member for receiving the distal end of the core wire. Preferably, the terminal member is secured to the core wire by brazing or solder, and advantageously, the terminal member is secured to the helical coil by brazing or soldering.

In a further embodiment of the invention the terminal member is of radiopaque material.

The invention will be more clearly understood from the following description of some embodiments thereof, which are given by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a side elevational view of a guide wire according to the invention,

Fig. 2 is a perspective view of a portion of the guide wire of Fig. 1,

Fig. 3 is another perspective view of the portion of Fig. 2 of the guide wire of Fig. 1,

Fig. 4 is a transverse cross-sectional view of the guide wire of Fig. 1,

Fig. 5 is a partly transverse cross-sectional side elevational view of a portion of the guide wire of Fig. 1,

Fig. 6 is another partly transverse cross-sectional side elevational view of the portion of Fig. 5 of the guide wire of Fig. 1,

Fig. 7 is a partly transverse cross-sectional plan view of the portion of Fig. 5 of the guide wire of Fig. 1,

Fig. 8 is a transverse cross-sectional side elevational view of a detail of the guide wire of Fig. 1,

Fig. 9 is a side elevational view of another portion of the guide wire of Fig. 1,

Fig. 10 is a transverse cross-sectional side elevational view of a portion of the guide wire of Fig. 1 with a portion of the guide wire curved,

Fig. 11 is a transverse cross-sectional side elevational view similar to Fig. 8 of a detail similar to that of Fig. 8 of a guide wire according to another embodiment of the invention, and

Fig. 12 is a transverse cross-sectional side elevational view similar to Fig. 8

of a detail similar to that of Fig. 8 of a guide wire according to another embodiment of the invention.

Referring to the drawings and initially to Figs. 1 to 9, there is illustrated a guide wire according to the invention, indicated generally by the reference numeral 1, for use in a re-canalising process for re-canalising a vascular occlusion in a vascular system of a human or animal subject. The guide wire 1 extends between a proximal end 3 and a distal end 4 and comprises a core wire 5 of stainless steel material which extends from the proximal end 3 to the distal end 4, and defines a central longitudinally extending axis 6. A terminal member 7 is secured to the core wire 5 at its distal end 4, and extends axially therefrom. The terminal member 7 tapers to a transversely extending distal chisel edge 8 for engaging and penetrating the occlusion or partial occlusion in a vessel of the vascular system as the guide wire 1 is urged through the vascular system. A sleeve, in this embodiment of the invention provided by a tightly coiled helical coil 10 of stainless steel material is secured to the terminal member 7 and extends therefrom over the core wire 5 and terminates at a location 11 intermediate the proximal end 3 and the distal end 4 of the guide wire 1, but towards the distal end 4. The helical coil 10 is of circular transverse cross-section, and defines a circular cross-section bore 12.

The terminal member 7 is of circular transverse cross-sectional area adjacent the helical coil 10, and is of radiopaque material, in this embodiment of the invention platinum alloy, so that it is visible under X-rays as the guide wire 1 is being urged through the vascular system. The diameter of the terminal member 7 is substantially

similar to the outer diameter of the helical coil 10 adjacent the terminal member 7 so that as a catheter is being urged along the guide wire 1, the catheter can readily easily be urged over the terminal member 7. The transverse width *w* of the chisel edge 8 is similar to the diameter of the terminal member 7, and the terminal member 7 defines a pair of tapering surfaces 14 which terminate in a radiused surface 15 of radius *r* which defines the chisel edge 8. The radiused surface 15 defining the chisel edge 8 is of radius which is sufficiently blunt to prevent the chisel edge 8 from penetrating a wall of a vessel of the vascular system, but is not so blunt as would prevent the chisel edge 8 penetrating an occlusion or a partial occlusion in a vessel of the vascular system. The tapering surfaces 14 define an included angle α, which is sufficiently acute for gradually opening the occlusion as the terminal member 7 is urged therethrough, while at the same time avoiding detaching any of the occluding material from the vessel, in order to avoid urging the occluding material forwardly with the guide wire 1.

In this embodiment of the invention the included angle α defined by the tapering surfaces 14 is approximately 15°, however, it is envisaged that the included angle defined by the tapering surfaces 14 may be any acute angle in the range 10° to 60°, although it is believed that it is preferable that the acute angle defined by the tapering surfaces 14 should lie in the range 12° to 30°. In this embodiment of the invention the radius *r* of the radiused surface 15 is approximately 0.075mm, although it is envisaged that the radius of the radiused surface 15 may lie in the range 0.02mm to 0.14mm, although it is believed that it is preferable that the radius *r* should lie within the range 0.05mm to 0.10mm.

A plug 17 extends axially from the terminal member 7 for engaging the bore 12 in the helical coil 10 at the distal end thereof. The diameter of the plug 17 is such that the difference in the diameter of the plug 17 and the diameter of the terminal member 7 is equal to twice the diameter of the wire forming the helical coil 10, so that when the plug member 17 is engaged in the bore 12 of the helical coil 10 the outer surface defined by the helical coil 10 coincides with the outer surface of the terminal member 7. A bore 19 extends axially into the plug 17 and into the terminal member 7 for accommodating the distal end 4 of the core wire 5 for securing the terminal member 7 to the core wire 5. In this embodiment of the invention the core wire 5 and the helical coil 10 are soldered to the terminal member 7 by solder 20 which fills the bore 19 and the distal portion of a bore 12 of the helical coil 10 for securing the terminal member 7 to the core wire 5 and the helical coil 10.

The core wire 5 commences to taper at a location 22 at the proximal side of the location 11 at which the helical coil 10 terminates, and tapers to its distal end 4. In this embodiment of the invention the core wire 5 tapers in steps as is illustrated in Fig. 4. The core wire 5 tapers from the location 22 to a first portion 23 of constant diameter, and tapers from the first portion 23 to a second portion 24 of constant diameter, and in turn tapers from the second portion 24 to a third portion 25 of constant diameter. A distal portion 28 extending from the third portion 25 at 29 to a distal tip 30 is flattened to form a spade-like portion which defines a pair of opposite major surfaces 32 and 33. The flattened spade-like distal portion 28 facilitates bending of the guide wire intermediate a location 35 and the terminal member 7 for

facilitating directing and aligning the guide wire 1 to a branching vessel of the vascular system for urging the guide wire 1 into the branching vessel. A reinforcing means, in this embodiment of the invention provided by a reinforcing rib 34 extends longitudinally along the major surface 32 of the distal portion 28 from the location 29 to the location 35 for minimising torsional twisting of the core wire 5 along the flattened distal portion 28. The distal portion 28 of the core wire 5 may be provided with the distal portion 28 curved in a major plane containing the central axis 6 and extending intermediate the major surfaces 32 and 33, as illustrated in Fig. 10. Such curving of the distal portion 28 would normally be carried out during manufacture of the core wire 5, and would facilitate in aligning the guide wire 1 with a branching vessel. When so curved, the distal portion 28 could also be bent between the location 35 and the terminal member 7 in a plane at 90° to the major plane in which the curve is formed. The bending of the distal portion 28 between the location 35 and the terminal member 7 could be carried out by a surgeon or paramedic prior to insertion of the guide wire into the vascular system of the subject.

In this embodiment of the invention the terminal member 7 is secured to the core wire 5 with the major plane defined by the distal portion 28 of the core wire 5 extending perpendicularly to a plane containing the chisel edge 8 and the central axis 6 and extending intermediate the tapering surfaces 14. This facilitates bending of the flattened distal portion 28 in the directions of the arrows A and B, see Fig. 7. However, it is envisaged that the terminal member 7 may be secured to the core wire 5 with the major plane defined by the distal portion 28 extending parallel to the plane containing the chisel edge 8 and the central axis 6 and extending intermediate

the tapering surfaces 14, and in which case, the guide wire 1 could be bent along the distal portion 28 in the direction of the arrows C and D, see Fig. 6.

In use, the guide wire 1 is urged through the vascular system of the subject towards the occluded vessel. On reaching the occluded vessel, the guide wire is gradually urged forward and the chisel edge 8 of the terminal member 7 engages the occlusion and commences penetration thereof. As the chisel edge 8 penetrates the occlusion, the tapering surfaces 14 commence to gradually open the occlusion, and further urging of the guide wire 1 causes the terminal member 7 to open the occlusion with the diameter of the opening corresponding to the diameter of the terminal member 7. Further urging of the guide wire 1 through the occlusion maintains the occlusion open with a diameter corresponding to that of the terminal member 7. Thereafter a catheter (not shown) is passed over the guide wire 1 and is guided into the occlusion. If the guide wire is carrying a balloon, stent or other therapeutic device, the device is located in the occlusion, and the guide wire 1 and the catheter (not shown) are removed.

Prior to entering the guide wire 1 into the vascular system of the subject, the guide wire 1 may be bent adjacent the terminal member 7 thereof by bending the distal portion 28 between the location 35 and the terminal member 7 in the direction of the arrows A or B for facilitating aligning of the terminal member 7 of the guide wire 1 with a branching vessel as the guide wire 1 is being urged through the vascular system. Additionally, as mentioned above, the guide wire 1 may be supplied with the distal portion 28 already curved as illustrated in Fig. 10, and if desired, the distal

portion may be bent in a plane perpendicularly to the major plane for further enhancing alignment of the guide wire with a branching vessel of the vascular system.

It is also envisaged that the terminal member may be provided with wells or holes on its outer surface, in particular, along its tapering surfaces 14 for retaining drugs or other compositions, liquid or otherwise, for assisting in urging of the guide wire 1 through the vascular system, and in particular, for assisting in urging the terminal member 7 through the occlusion or partial occlusion. Such drugs or other compositions, which may be in liquid, powder or other suitable form, may be drugs which would facilitate in dilation of a vessel, or dissolving the material of the occlusion, for example, if the occlusion were caused by a thrombosis, one of the drugs may be suitable for dissolving the thrombosis.

Referring now to Fig. 11, a terminal member, indicated generally by the reference numeral 40, for securing to the distal end of a guide wire similar to the guide wire 1 is illustrated. The terminal member 40 is substantially similar to the terminal member 7, and similar components are identified by the same reference numerals. In this embodiment of the invention the terminal member 40 terminates in a chisel edge 8 similar to the chisel edge 8 of the terminal member 7. However, while an axial bore 19 extends into the terminal member 40 for engaging the distal end 4 of the core wire 5, the terminal member 40 is provided without a plug similar to the plug 17 of the terminal member 7. In this case the helical coil 10 would be provided to abut an end face 41, and would be brazed or soldered to the end face 41 with the outer

surface defined by the helical coil coinciding with the outer surface defined by the terminal member 40. The soldering or brazing of the helical coil to the end face 41 of the terminal member 40 could be carried out simultaneously with soldering or brazing the core wire 5 into the bore 19 of the terminal member 40, or after the terminal member 40 had been brazed or soldered to the core wire 5.

Referring now to Fig. 12, there is illustrated a terminal member 50 for use with a guide wire similar to the guide wire 1. The terminal member 50 is substantially similar to the terminal member 7 and similar components are identified by the same reference numerals. In this embodiment of the invention an axial plug 17 extends from the terminal member 50, however, the terminal member 50 is provided without an axial bore similar to the axial bore 19 which was provided in the terminal member 7. Thus, in this embodiment of the invention the axial plug 17 would engage the bore helical coil, and the core wire 5 adjacent its distal end 4 would be provided in abutting engagement with an end face 51 of the terminal member 50 and brazed or soldered thereto.

While the sleeve extending around the core wire 5 adjacent its distal end has been described as being provided by a helical coil, any other suitable sleeve may be provided, for example, in certain cases, it is envisaged that the sleeve may be provided as a sleeve of plastics material, composite polymer material, or any other polymer material.

It will be appreciated that the guide wire may be produced of materials other than

those described, for example, the core wire may be of any other suitable material besides stainless steel, for example, nickel titanium alloy, MP35N, composite polymers, and the like. Similarly, the helical coil or other sleeve may be of any other suitable material besides stainless steel, for example, nickel titanium alloy, MP35N, composite polymers, and the like, and the terminal member may be of any other material besides platinum alloy, however, it is important that the terminal member should be of a radiopaque material. Needless to say, any other suitable securing means for securing the terminal member to the core wire and to the helical coil or other sleeve may be used besides soldering and brazing. Indeed, in certain cases, it is envisaged that the terminal member may be secured to the core wire and the helical coil or other sleeve by adhesive or any other suitable securing means.

The invention is not limited to the embodiments hereinbefore described, which may be varied in construction and detail.

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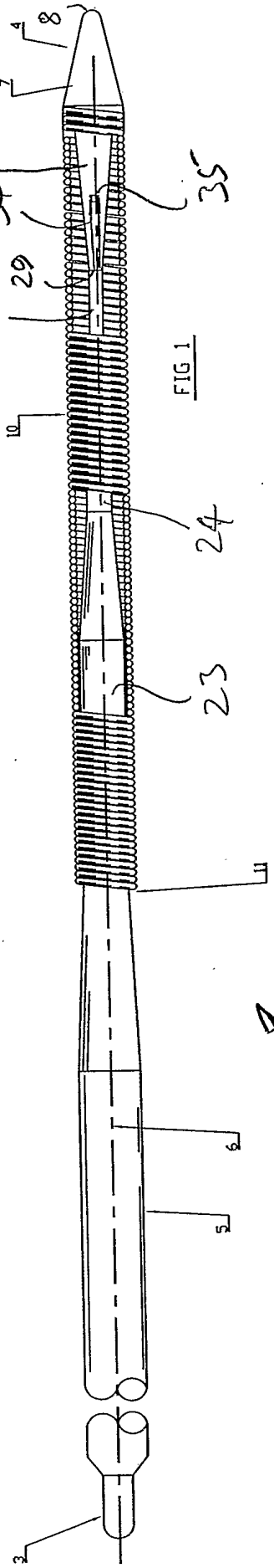


FIG 1

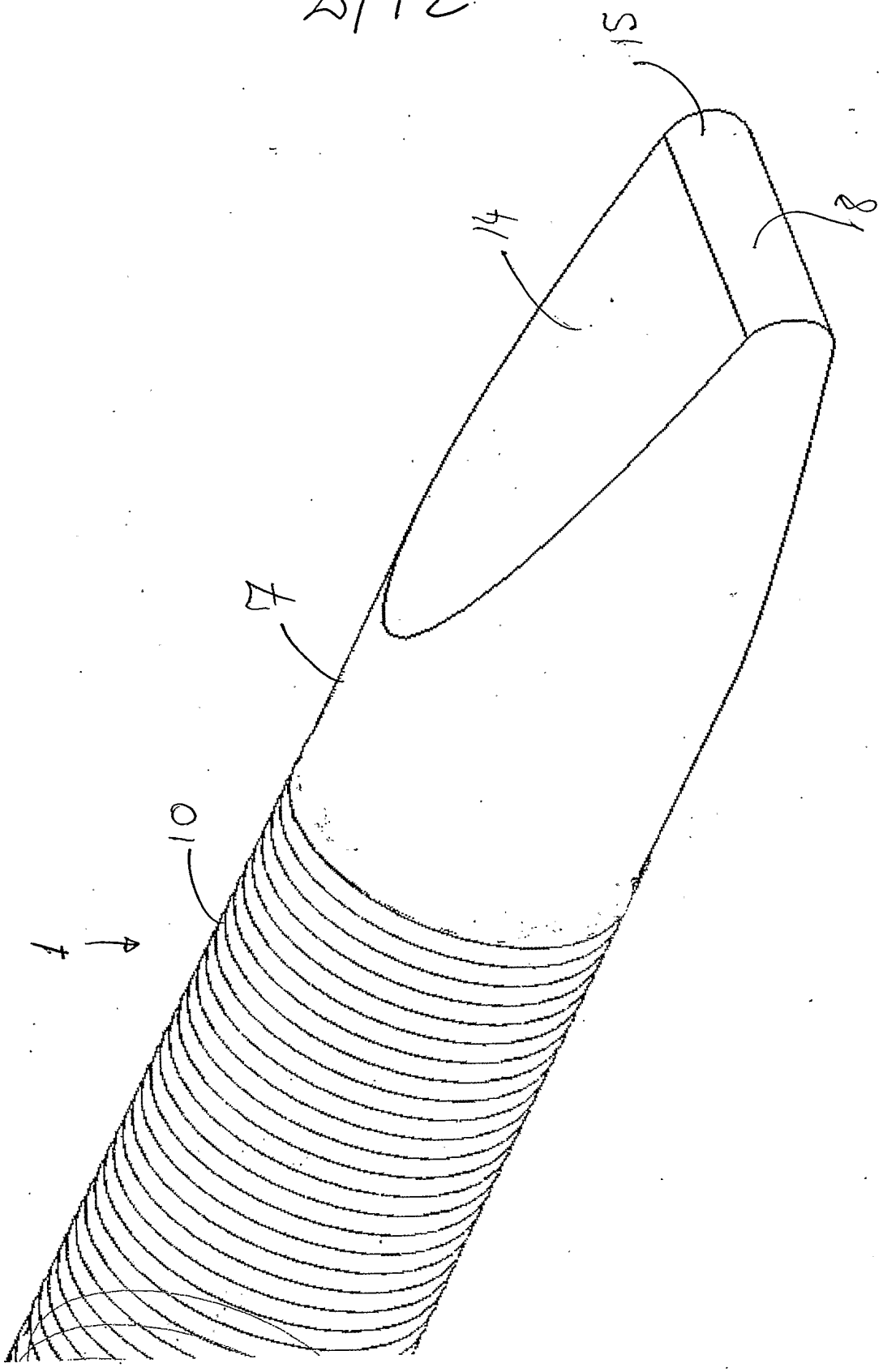


Fig 2

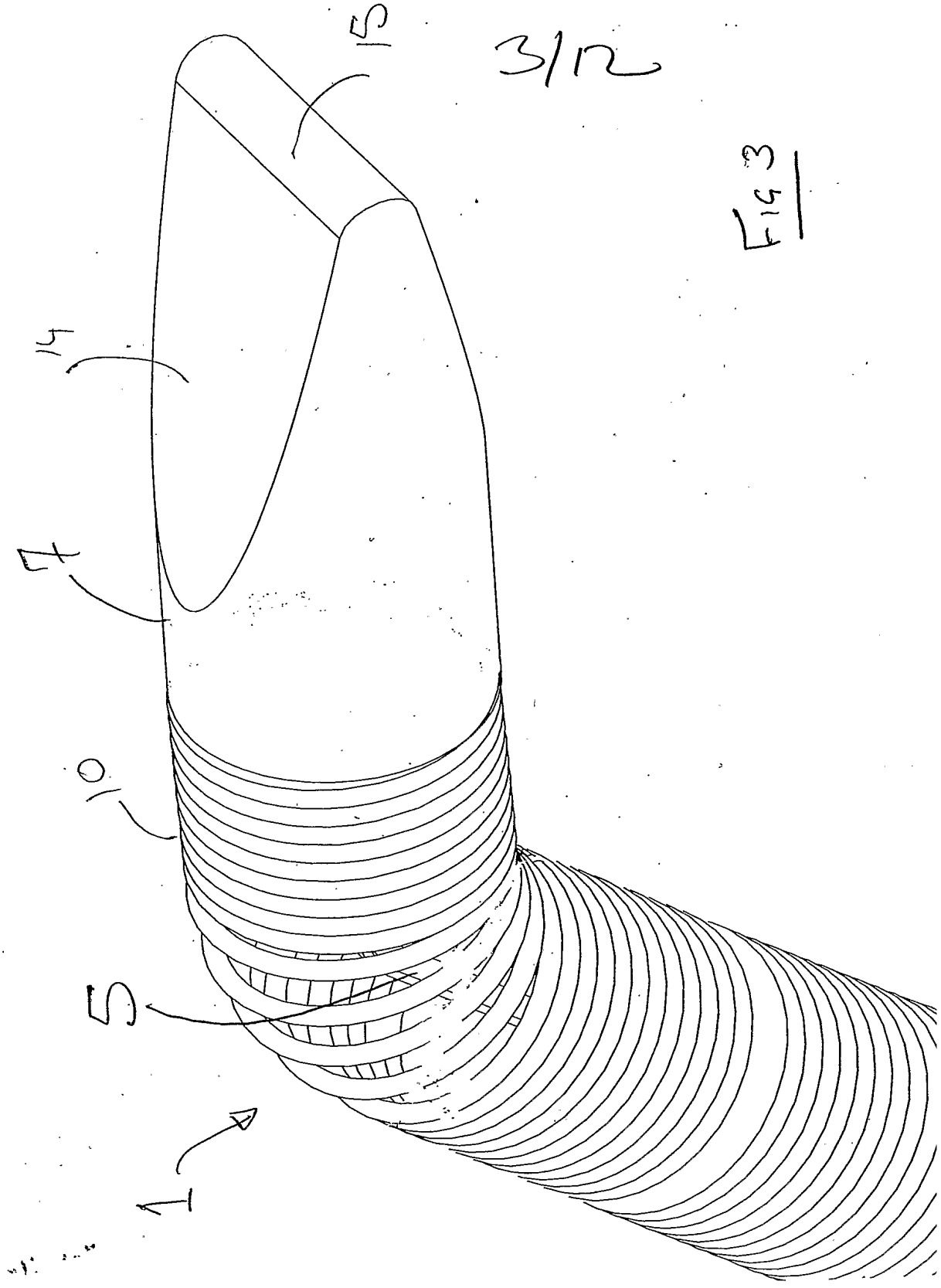


FIG 3

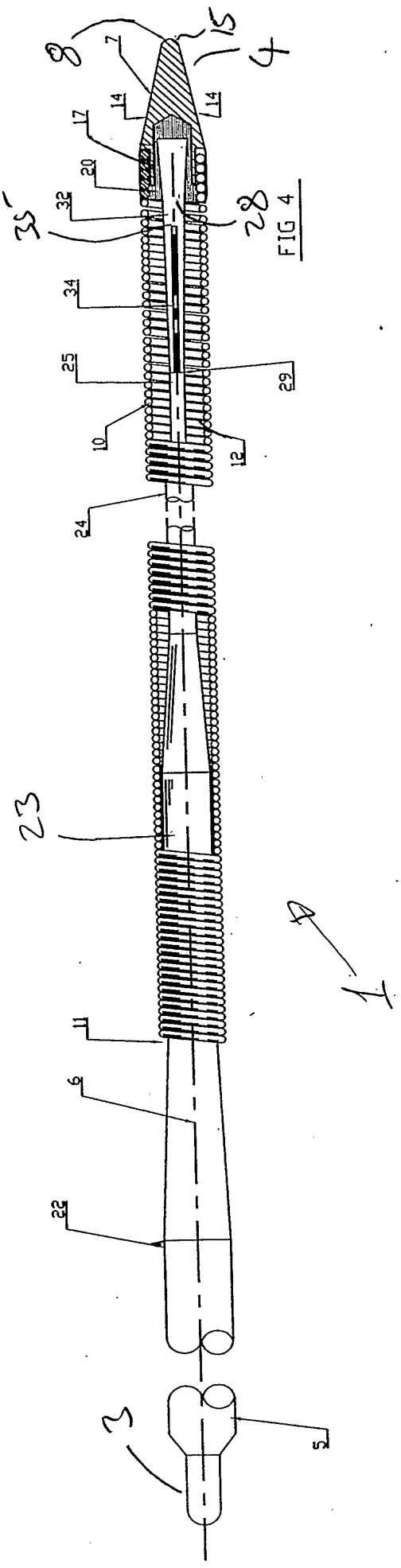


FIG 4

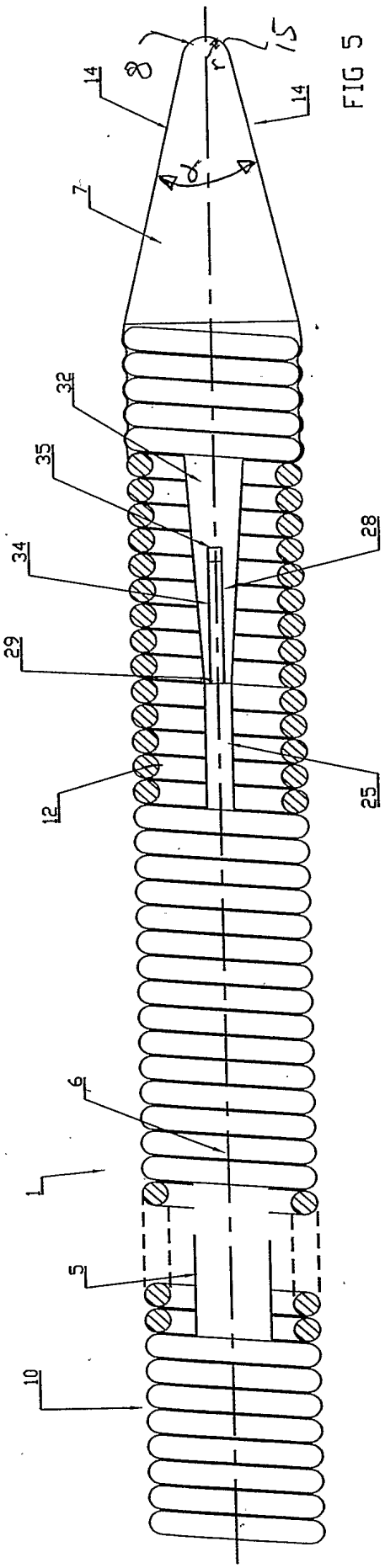


FIG 5

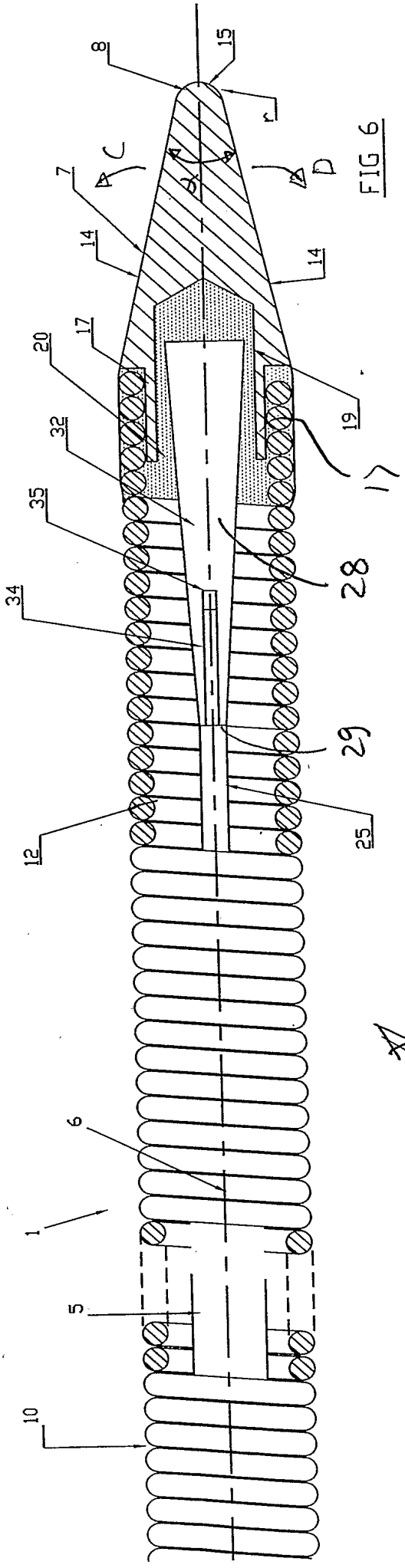


FIG 6

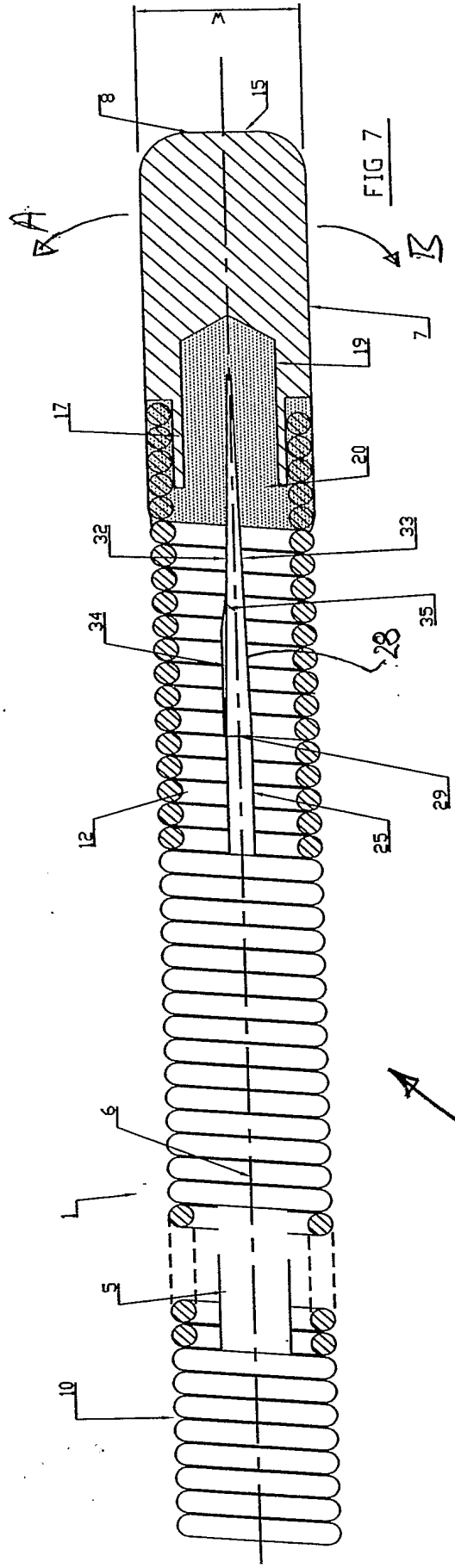
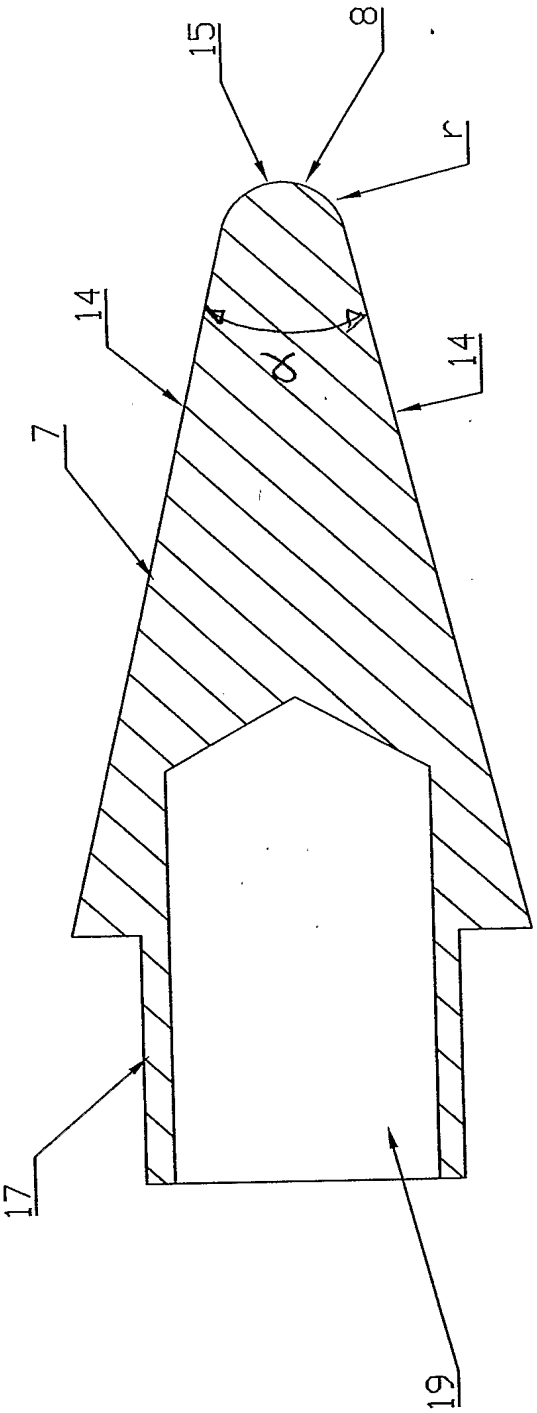


FIG 7

FIG 8



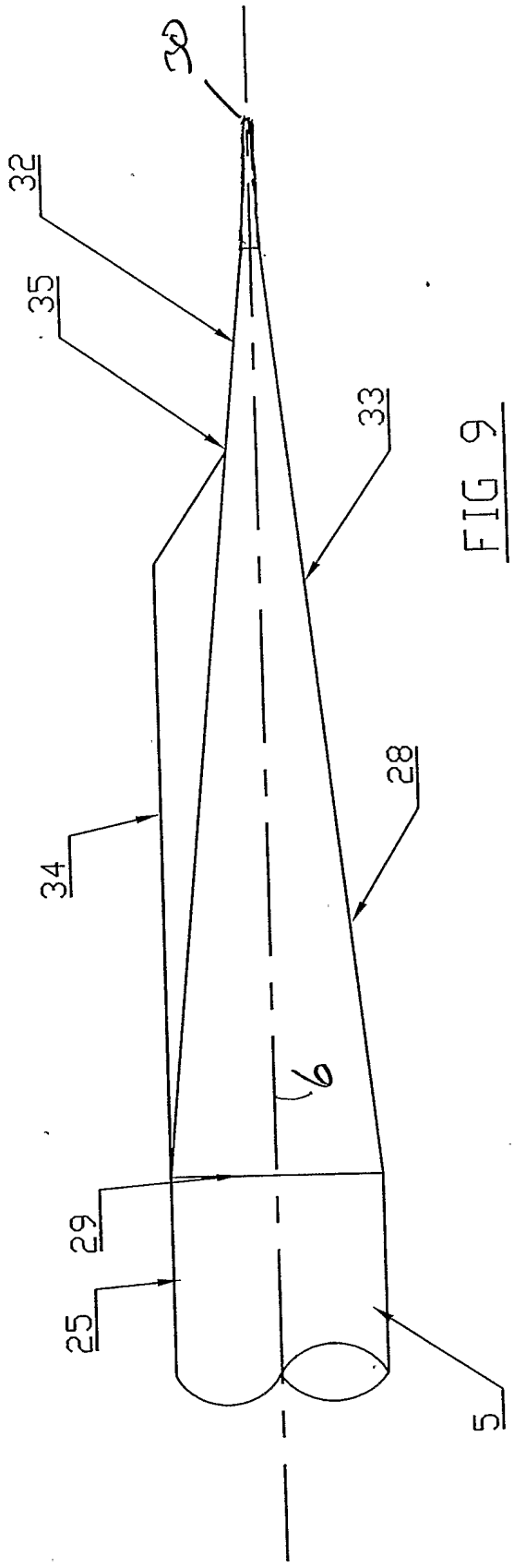


FIG 9

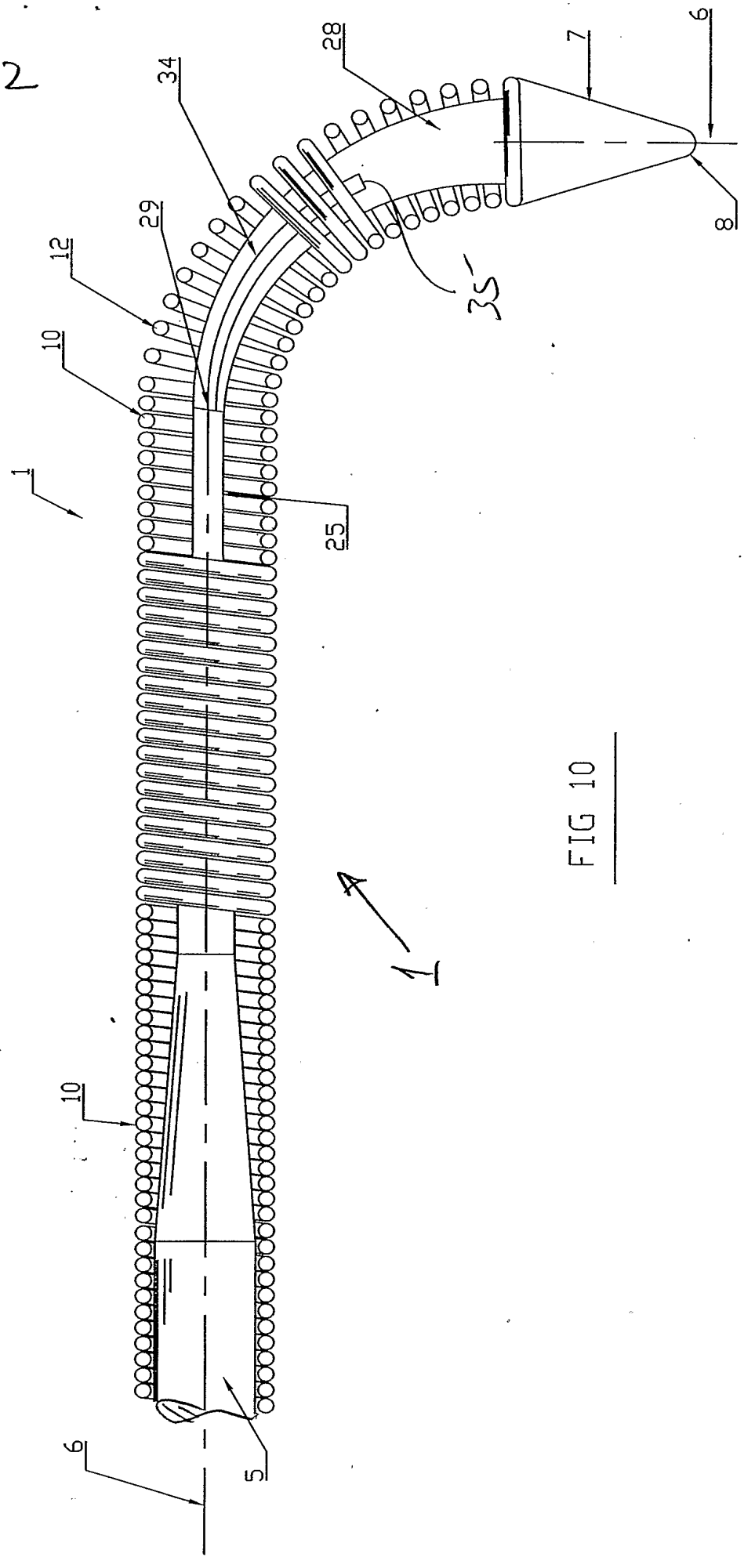


FIG 10

FIG 11

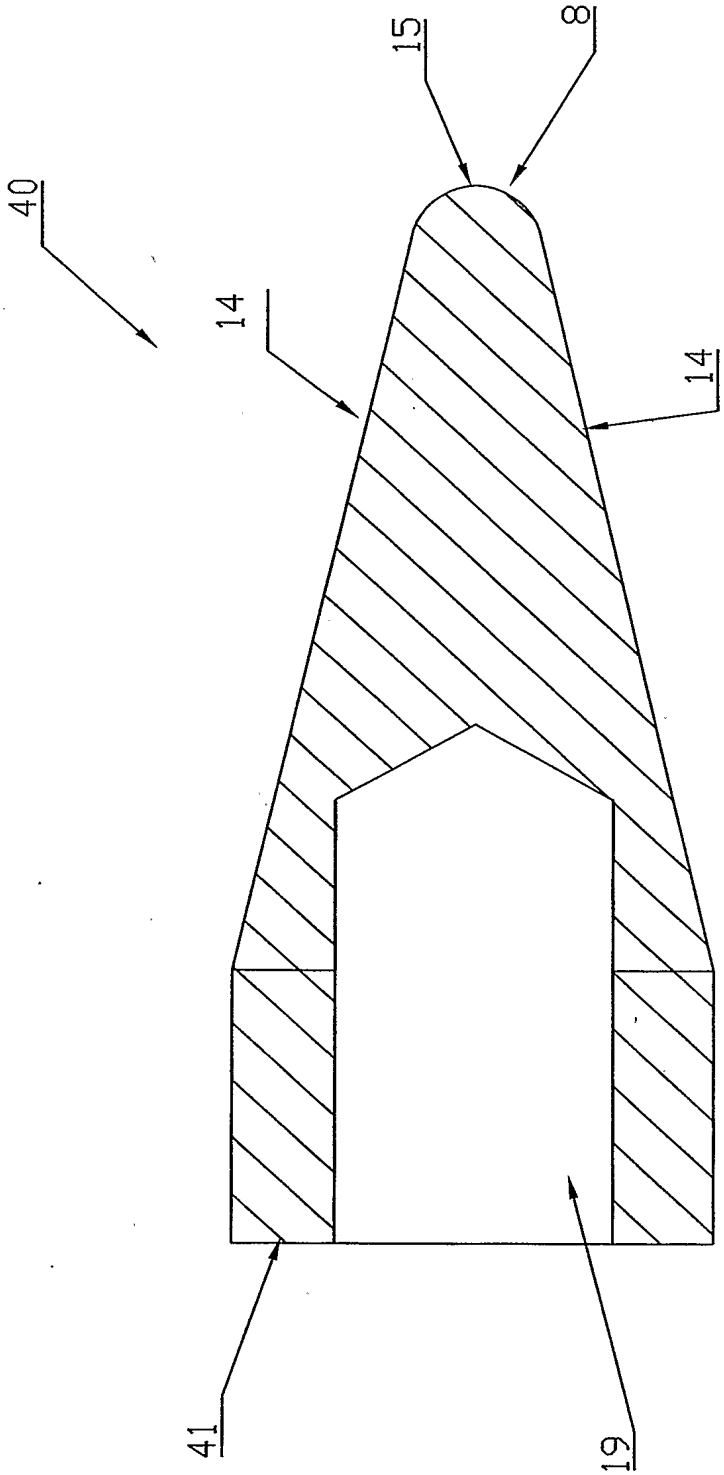


FIG 12